

*Sub C4*

an energy delivery device including a proximal portion and a distal portion with a blunt periphery positionable in contact with a surface of [configured to be positioned at an interface between the fluid medium and] the selected site without penetrating the surface of the selected site and configured to provide a selected thermal distribution in the selected site and effect a controllable contraction of at least a portion of the selected site;

a sensor positioned at the distal portion of the ~~energy delivery device~~; and

a feedback control system coupled to the sensor, wherein a position of the sensor, a geometry of the distal portion of the energy delivery device and the feedback control system provide a controllable energy delivery to the selected [containing tissue] site.

#### REMARKS

In the instant Office Action, the Examiner has indicated that the rejections set forth in the previous Office Action of January 21, 1998 are repeated:

Claims 1, 3-7, 9, 10, 12-20, 23-27 and 29 are rejected under 35 U.S.C. §102(b) as being clearly anticipated by Makower or Edwards et al.

Claims 2, 8, 11, 21, 22 and 28 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Makower or Edwards et al. The Examiner notes that Makower and Edwards teach a device as claimed except for the use of platinum band type sensors, thermistor type sensors, resistive heaters or the use of potting compound. The Examiner then states that it would have been obvious to the artisan of ordinary skill to employ the sensors, heaters, electrical material and sensor location with potting compound.

Additionally, the Examiner has noted in the instant Office Action that both Edwards, et al. and Makower disclose devices which require traumatic insertion into tissue, and further notes that requiring that the distal portion be "configured to be positioned at an interface between fluid medium and the selected sites does not provide additional structure to the device," and goes on to state that "even if a further limitation were construed, the devices of Edwards, et al. and Makower are also so configured, since they will not be destroyed or rendered non-functional by such positioning."

Independent claims 1 and 29 specify an apparatus for effecting a change in at least a portion of a selected site of a collagen containing tissue that is adjacent to a fluid medium. Claims 1 and 29 are also amended to specify the apparatus as having and a distal portion with a blunt periphery positionable in contact with a surface of the selected site without penetrating the surface of the selected site.

In contrast, Edwards et al. teaches a medical probe device comprising a catheter having a stylet guide housing with one or more stylet ports in a side wall thereof and guide means for directing

a flexible stylet outward through the stylet port and through intervening tissue. "The stylet preferably has a sharpened end to reduce resistance and trauma when it is pushed through tissue to a target site." See column 5, lines 25-27. Further, "The stylet is shaped to facilitate easy passage through tissue." See column 5, line 17-18. As a result, Edwards does not teach a blunt periphery.

Further, Makower teaches a catheter including at least one fiber optic element for delivering laser light from a laser energy source to the area for prostate treatment. The fiber optic element is slidably received in and carried by a hollow needle. The hollow needle has a sharpened distal end in order to easily mechanically puncture the passageway wall and enter the organ to carry the fiber optic element to the area to be treated. See page 4, lines 18-23. As a result, Makower also does not teach a blunt periphery.

Neither Makower nor Edwards teach an apparatus with a blunt periphery positionable in contact with a surface of the selected site without penetrating the surface of the selected site. As a result, the rejection under 35 U.S.C. §102(b) should be withdrawn.

### CONCLUSION

It is submitted that the present application is in form for allowance, and such action is respectfully requested.

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. 23-2415 (Docket No. 17616-705). A duplicate copy of this paper is enclosed.

Respectfully submitted,

WILSON SONSINI-GOODRICH & ROSATI

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Paul Davis, Reg. No. 29,294

650 Page Mill Road  
Palo Alto, CA 94304  
(650) 493-9300